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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER SASAN, ARADHANA	
			ART UNIT	PAPER NUMBER
			1615	
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			10/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No. 10/511,594	Applicant(s) NGUYEN-KIM ET AL.	
	Examiner ARADHANA SASAN	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 16-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/22/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction Response

1. Applicant's election with traverse of Group II (claims 7-15) in the reply filed on 07/10/08 is acknowledged.

The traversal is on the ground(s) that product, method of making, and the use thereof are considered related inventions under 37 C.F.R. § 1.475(b) and unity of invention between the [inventions] exist. Applicant traverses on the additional grounds that the Office has not shown that a burden exists in searching the entire application. Applicant argues that the Office has not shown any evidence that restriction should now be required when the International Preliminary Report did not and that the restriction is believed to be improper.

This is not persuasive because this application is a national stage entry of PCT/EP03/04647. The technical feature linking groups I-V is a copolymer A). Lede (in US 2001/0026791) discloses copolymers of methacrylamides and vinylpyrrolidones (Page 2, [0019]). Component c of instant claim 7 can have 0% by weight of a water soluble compound. Therefore, claims 7-15 (drawn to a copolymer A) are anticipated by the disclosure of Lede and lack novelty. Therefore, the technical feature linking the inventions of groups I-V does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

Since the instant composition claims do not share a special technical feature with the copolymer claims, process for preparing copolymer claims, method of coating a

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substrate claims and method of making a pharmaceutical composition claims, as such, unity between the above Groups I – V is broken.

Therefore, the restriction requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-6 and 16-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

3. Claims 7-15 are included in the prosecution.

Priority

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 9/22/06 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement.

See attached copy of PTO-1449.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7, component b) recites “0 to 90% by weight, based on the total weight of components a) to d), of at least one α , β -ethylenically unsaturated amide-containing compound of the formula I ...” If there is 0% of component b), it is unclear how there can be “at least one” α , β -ethylenically unsaturated amide-containing compound. This discrepancy in the claim makes it indefinite.

Claim 7, component c) recites “0 to 40% by weight, based on the total weight of components a) to d), of at least one unsaturated, water-soluble compound ...” If there is 0% of component b), it is unclear how there can be “at least one” unsaturated, water-soluble compound. This discrepancy in the claim makes it indefinite.

Claim 7 also recites: “...the proportion by weight of the sum of components b) and c) is at least 5% by weight ...”. If components b) and c) are 0%, it is unclear how the proportion by weight of the sum of components b) and c) would be “at least 5%” by weight. This discrepancy in the claim makes it indefinite.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

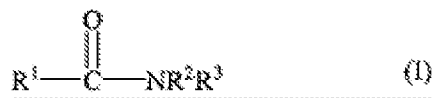
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by GB 1,357,391 ('391 hereinafter).

The claimed invention is a copolymer A) obtained by free-radical copolymerization of:

a) 5 to 90% by weight, based on the total weight of components a) to d), of acrylamide and/or methacrylamide,

b) 0 to 90% by weight, based on the total weight of components a) to d), of at least one α , β -ethylenically unsaturated amide-containing compound of the formula I



where R^1 is a group of the formula $\text{CH}_2=\text{CR}^4$ - where $\text{R}^4=\text{H}$ or $\text{C}_1\text{-C}_4\text{-alkyl}$, and R^2 and R^3 , independently of one another, are each H, alkyl, cycloalkyl, heterocycloalkyl, aryl or hetaryl, with the proviso that one of the radicals R^2 or R^3 is different from H, or R^2 and R^3 together with the nitrogen atom to which they are bonded are a five- to eight-membered heterocycle, or R^2 is a group of the formula $\text{CH}_2=\text{CR}^4$ – and R^1 and R^3 , independently of one another, are each H, alkyl, cycloalkyl, heterocycloalkyl, aryl or

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hetaryl, or R^1 and R^3 together with the amide group to which they are bonded are a lactam with 5 to 8 ring atoms,

c) 0 to 40% by weight, based on the total weight of components a) to d), of at least one unsaturated, water-soluble compound, which is different from components a) and b), and copolymerizable therewith, where the proportion by weight of the sum of components b) and c) is at least 5% by weight, optionally in the presence of up to 25% by weight, based on the total weight of components a) to d), of at least one water-soluble component d), which is selected from the group consisting of:

d1) polyether-containing compounds,

d2) polymers which have at least 50% by weight repeat units derived from vinyl alcohol,

d3) starch and starch derivatives, and mixtures thereof.

'391 teaches a copolymer of 70 parts of methacrylamide, 27.5 parts of vinylpyrrolidone and 2.5 parts of vinyl imidazole (Page 5, lines 16-19).

Regarding instant claim 7, the limitations of components a), b) and c) are anticipated by the methacrylamide, vinylpyrrolidone, and vinylimidazole taught by '391 (Page 5, lines 16-19). The limitation of component d) is anticipated by '391 because instant claim 7 recites that component d) is optional. The levels of components a), b) and c) are anticipated by the 70 parts of methacrylamide, 27.5 parts of vinylpyrrolidone and 2.5 parts of vinyl imidazole taught by '391 (Page 5, lines 16-19).

Therefore, the limitations of claim 7 are anticipated by the teachings of '391.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 8, 11-12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1,357,391 ('391).

The teaching of '391 is stated above.

'391 does not expressly teach the range of methacrylamide at 10-45% by weight, based on the total weight of components a) to d).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a copolymer with methacrylamide, vinylpyrrolidone, and vinylimidazole, as suggested by '391, modify the level of methacrylamide and vinylpyrrolidone during the process of routine experimentation, and produce the instant invention.

One of ordinary skill in the art would do this because during the process of routine experimentation the levels of these components (methacrylamide and vinylpyrrolidone) would be manipulated with a reasonable expectation of success of producing a functional copolymer.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed

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invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 8, 11, 12, and 15, the methacrylamide, vinylpyrrolidone and water soluble compound would have been obvious over the 70 parts of methacrylamide, 27.5 parts of vinylpyrrolidone and 2.5 parts of vinylimidazole taught by '391 (Page 5, lines 16-19). The levels of components a), b) and c) would have been obvious variants over the levels of methacrylamide, vinylpyrrolidone and vinylimidazole as taught by '391 (Page 5, lines 16-19). During the process of routine experimentation these levels can be modified, unless there is evidence of criticality or unexpected results. Instant claims 8 and 12 recite that component d) is optional.

12. Claims 9-10 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1,357,391 ('391) in view of Lede et al. (US 2001/0026791 A1).

The teaching of '391 is stated above.

'391 does not expressly teach polymers of d2).

Lede teaches copolymers of acrylic acid or methacrylic acid with monomers selected from the group consisting of methacrylamides and vinylpyrrolidones (Page 2, [0019]). Vinyl alcohols and vinylcaprolactam as monomers for film-forming, hair-fixing polymers are also taught by Lede (Page 1, [0016], Page 2, [0018] & [0023]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a copolymer with methacrylamide, vinylpyrrolidone, and

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vinylimidazole, as suggested by '391, combine it with the vinyl alcohol components, as taught by Lede, and produce the instant invention.

One of ordinary skill in the art would do this because Lede teaches that vinyl alcohol is one of the monomers which can be used in a film-forming, hair-fixing copolymer (Page 1, [0016]).

Regarding instant claim 9, the limitations of methacrylamide and vinylpyrrolidone would have been obvious over the methacrylamide and vinylpyrrolidone taught by '391 (Page 5, lines 16-19) and by Lede (Page 2, [0019]). The limitation of component d2) would have been obvious over the vinyl alcohol taught by Lede (Page 1, [0016], Page 2, [0018] & [0023]). The level of components a), b) and d2) would have been obvious variants over the levels of methacrylamide and vinylpyrrolidone as taught by '391 (Page 5, lines 16-19). During the process of routine experimentation levels of these monomers can be modified, unless there is evidence of criticality or unexpected results.

Regarding instant claim 10, the limitations of methacrylamide and vinylpyrrolidone would have been obvious over the methacrylamide and vinylpyrrolidone taught by '391 (Page 5, lines 16-19) and by Lede (Page 2, [0019]). The limitation of vinylcaprolactam would have been obvious over the vinylcaprolactam taught by Lede (Page 1, [0016]). The level of methacrylamide, vinylpyrrolidone and vinylcaprolactam would have been obvious variants over the levels of methacrylamide and vinylpyrrolidone as taught by '391 (Page 5, lines 16-19). During the process of routine experimentation levels of these monomers can be modified, unless there is evidence of criticality or unexpected results.

Regarding instant claim 13, the methacrylamide, vinylpyrrolidone and vinylimidazole would have been obvious over the 70 parts of methacrylamide, 27.5 parts of vinylpyrrolidone and 2.5 parts of vinylimidazole taught by '391 (Page 5, lines 16-19). The limitation of d2) polymers would have been obvious over the vinyl alcohols taught by Lede (Page 1, [0016], Page 2, [0018] & [0023]). The levels of components a), b) and c) would have been obvious variants over the levels of methacrylamide, vinylpyrrolidone and vinylimidazole as taught by '391 (Page 5, lines 16-19). One with ordinary skill in the art would modify the level of d2) because this is a modifiable parameter. During the process of routine experimentation these levels can be modified, unless there is evidence of criticality or unexpected results.

Regarding instant claim 14, the methacrylamide, vinylpyrrolidone and vinylimidazole would have been obvious over the 70 parts of methacrylamide, 27.5 parts of vinylpyrrolidone and 2.5 parts of vinylimidazole taught by '391 (Page 5, lines 16-19). The limitation of vinylcaprolactam would have been obvious over the vinylcaprolactam as a monomer for film-forming, hair-fixing polymers, as taught by Lede (Page 1, [0016]). The levels of components a), b) and c) would have been obvious variants over the levels of methacrylamide, vinylpyrrolidone and vinylimidazole as taught by '391 (Page 5, lines 16-19). During the process of routine experimentation these levels can be modified, unless there is evidence of criticality or unexpected results.

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13. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lede et al. (US 2001/0026791 A1).

Lede teaches copolymers of acrylic acid or methacrylic acid with monomers selected from the group consisting of methacrylamides and vinylpyrrolidones (Page 2, [0019]). Vinyl alcohols are also taught by Lede (Page 1, [0016], Page 2, [0018] & [0023]).

Lede does not expressly teach the percent by weight of methacrylamide and vinylpyrrolidone.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a copolymer with methacrylamide and vinylpyrrolidone, as suggested by Lede, modify the level of the methacrylamide and vinylpyrrolidone during the process of routine experimentation, and produce the instant invention.

One of ordinary skill in the art would do this because during the process of routine experimentation the levels of these components (methacrylamide and vinylpyrrolidone) would be manipulated with a reasonable expectation of success of producing a functional copolymer.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 7, the limitation of components a) and b) would have been obvious over the copolymers with monomers of methacrylamides and vinylpyrrolidones, as taught by Lede (Page 2, [0019]). The limitations of components c) and d) would have been obvious over the copolymer taught by Lede because instant claim 7 recites that component c) can be 0% by weight, and that component d) is optional. The level of components a) and b) would have been obvious variants during the process of routine experimentation unless there is evidence of criticality or unexpected results.

Regarding instant claim 8, the limitation of components a) and b) would have been obvious over the copolymers with monomers of methacrylamides and vinylpyrrolidones, as taught by Lede (Page 2, [0019]). The limitations of components c) and d) would have been obvious because instant claim 8 recites that component c) can be 0% by weight, and that component d) is optional. The level of components a) and b) would have been obvious variants during the process of routine experimentation unless there is evidence of criticality or unexpected results.

Regarding instant claim 9, the limitation of methacrylamide and vinylpyrrolidone would have been obvious over the methacrylamides and vinylpyrrolidones, as taught by Lede (Page 2, [0019]). The limitation of the d2) polymers would have been obvious over the vinyl alcohols taught by Lede (Page 1, [0016], Page 2, [0018] & [0023]). The level of the components (a), b) and d2)) would have been obvious variants during the process of routine experimentation unless there is evidence of criticality or unexpected results.

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Regarding instant claim 10, the limitation of methacrylamide and vinylpyrrolidone would have been obvious over the methacrylamides and vinylpyrrolidones, as taught by Lede (Page 2, [0019]). The limitation of vinylcaprolactam would have been obvious over the vinylcaprolactam taught by Lede (Page 1, [0016]). The level of methacrylamide, vinylpyrrolidone and vinylcaprolactam would have been obvious variants during the process of routine experimentation unless there is evidence of criticality or unexpected results.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 7, 8, 12, 13 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 12 of U.S. Patent No. 5,869,032 ('032 hereinafter). Although the conflicting claims are not

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identical, they are not patentably distinct from each other because instant claims and claims of '032 are drawn to a polymer obtained by free radical copolymerization of a monomer mixture comprising vinylimidazole, vinylcaprolactam, vinylpyrrolidone and methacrylamide. The difference between instant claims and those of '032 is the weight percent ranges of the monomers. However, one with ordinary skill in the art would find it obvious to modify the levels of monomers during the process of routine experimentation and the recited weight percent ranges would have been obvious variants unless there is evidence of criticality or unexpected results.

16. Claims 7, 8, 12, 13 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11 and 15 of copending Application No. 11/576,612 ('612 hereinafter). Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims and claims of '612 are drawn to a polymer containing a monomer mixture comprising vinylimidazole, vinylcaprolactam, vinylpyrrolidone and methacrylamide. The difference is that claims of '612 do not specify the weight percent ranges of the monomers. However, one with ordinary skill in the art would find it obvious to modify the levels of monomers during the process of routine experimentation and the recited weight percent ranges would have been obvious variants unless there is evidence of criticality or unexpected results.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

17. No claims are allowed.
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615